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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,955	10/28/2003	Robert Naylor Laurie	P07351US01/BAS	3799
881 7590 06/30/2010 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 06/30/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/693,955	Applicant(s) LAURIE ET AL.
Examiner Humera N. Sheikh	Art Unit 1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: 1, 3, 4, 8, 10, 13 and 15.
 Claim(s) objected to: _____.
 Claim(s) rejected: 11, 12 and 14.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

Continuation of 11, does NOT place the application in condition for allowance because:

Applicant argued, "Howard fails to provide an enabling disclosure for one of ordinary skill in the art to produce a trace element solution comprising a metal concentration of 60 mg/ml. Howard would not have allowed one of ordinary skill in the art to produce a trace element solution having a metal concentration of 60 mg/ml, let alone 72 mg/ml as alleged by the Examiner. All examples in Howard include a substantially smaller concentration than the 60 mg/ml."

Applicant's arguments have been considered but were not found persuasive. The disclosure of Howard is enabling for the production of a trace element solution having a possible 72 mg/ml total metal concentration, since Howard explicitly teaches and suggests suitable and effective ranges for each of the trace elements claimed. Applicant is arguing and emphasizing the preferred embodiments of Howard (at column 5, lines 40-59) and is disregarding the fact that Howard vividly discloses ranges of both low and high amounts of trace elements, whereby one of ordinary skill in the art would choose higher amounts of the trace elements, if so desired. The reference at column 5, lines 26-39, is clearly suggestive of effective ranges, whereby high amounts of the trace elements is taught and therefore, can be used. Moreover, Applicant is also arguing the lower amounts used in the Examples of Howard, namely, Examples 1 and 2. However, the Examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Furthermore, the teachings of the prior art are not limited to the examples disclosed therein.

Applicant argued, "Howard fails to be an anticipatory reference of claims 11, 12 and 14."

This was not persuasive. The Examiner reminds Applicant that the claims (11, 12, 14 and 16) have been rejected under 35 U.S.C. §103(a) and not under 35 U.S.C. §102. Thus, one of ordinary skill in the art would find the instant invention *prima facie* obvious, at the time the invention was made, based on the teachings of Howard. Howard explicitly teaches and suggests effective ranges for each of the trace elements claimed, including both low and high amounts of trace elements, which would read on the concentration levels as claimed (60 mg/ml).

Applicant argued, "The reason the Howard method would be insufficient for producing the higher concentrations required include the fact that Howard discloses a method of producing individual trace element solutions which are combined together to form a single trace element solution comprising all of its trace elements and thus discloses a batch method".

This argument was not persuasive. Note that the rejected claims are drawn to "product" claims and not process of making claims, nor product-by-process claims. As such, the process by which the product is formed does not impart patentable weight. The claims are merely drawn to an "injectable trace element solution", indicative of product claims. Moreover, Howard recognizes ranges of trace elements, whereby the upper limit claimed would read on the "60 mg/ml" claimed by Applicant.

Applicant argued, "Howard uses tetrasodium EDTA, whereas the present invention uses EDTA and/or disodium EDTA."

This was not persuasive. Note that none of claims 11, 12 or 14 recite any reference to EDTA and/or disodium EDTA. The claims merely claim an "injectable trace element solution", with no mention of EDTA and/or disodium EDTA, as argued by Applicant. Hence, the tetrasodium EDTA of Howard is permissible, given the present claim language. Further, for the reasons advanced in the Final Rejection (filed 3/16/10), Applicant's arguments were not deemed persuasive.